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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,799	01/02/2002	Wolfgang Werr	13054.02140	7938

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BAKER & BOTTS
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NEW YORK, NY 10112

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/08/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File copy*

Application No.

09/890,799

Applicant(s)

WERR, WOLFGANG

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Europe on February 9, 2000. It is noted, however, that Applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10, 13, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota (EP0724888).

Kubota discloses a material comprising a polymer having a sol-gel transition temperature in an aqueous solution thereof and assuming a liquid state at a temperature lower than the sol-gel transition temperature, and a gel state at a temperature higher than the sol-gel transition temperature (See col. 4, lines 47-54), as claimed in claim 1 of the instant application. The limitation in instant claim 1, reading “of the type injected into vascular lumens to solidify and occlude said lumens” is feature intended use and, as such, has no patentable weight in composition claims.

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With regard to claims 2 and 16, Kubota discloses plural blocks having a cloud point and a compound comprising a plurality of blocks having a cloud point , and a hydrophilic block bonded thereto (See col. 11, lines 29-49).

Regarding claims 3 and 4, Kubota discloses the same plurality of blocks and hydrophilic block claimed by Applicant (See col. 11, line 29 to col. 12, line 50).

With respect to claim 5, Kubota teaches that the polymer has a sol-gel transition temperature between 0° and 40°C (See col. 6, lines 44-47).

With regard to claims 6-10, Kubota teaches that the material of the invention comprises active agents, and specifically cytokines, including the growth factors claimed by Applicant in claim 8, and extracellular matrixes, including the compounds claimed by Applicant in claim 9 (See col. 16, line 40 to col. 17, line 17). The cytokines disclosed by the prior art are antineoplastic agents, as claimed by Applicant in claim 10.

Regarding claims 13 and 14, Kubota teaches that the composition of the invention may include alcohols and oils (See col. 18, lines 14-27). Alcohols and oils alter the sol-gel transition temperature and the viscosity of the solution, as claimed by Applicant.

The compositions disclosed by Kubota meet the limitations of claims 1-10, 13, 14 and 16 of the instant application, as the prior art contemplates liquid compositions comprising a polymer

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having a sol-gel transition temperature, as claimed by Applicant. Thus, Kubota anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubota, as applied to claims 1-10, 13, 14 and 16 above, and further in view of Tautvydas et al. (U.S. Patent 5,407,445).

The teachings of Kubota have been summarized above. With respect to claims 11 and 12, Kubota fails to specifically include radiopaque agents among the active agents comprised in the material of the invention. With regard to claim 15, Kubota does not provide a method for occluding a vascular lumen.

Tautvydas et al. discloses an aqueous solution comprising polyoxyethylene/polyoxypropylene block copolymers, which are liquid at room temperature and gel at body temperature for implantation into lumens (See col. 4, lines 1-42 and Examples I-III). The patent teaches that the gelling compositions of the invention comprise a salt, which decreases radiolucency, i.e. renders the implant radiopaque (See col. 10, line 54 to col. 11, line 49).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Kubota, by including a radiopaque agent, such as a salt, as taught by Tautvydas et al., to render the implant radiopaque, and devise a method for occluding a vascular lumen comprising injecting an implant, which fills the lumen, as disclosed in the U.S. Patent. The expected result would have been a successful implant comprising a radiopaque material and a successful method of prosthesis. Because of the teachings of Kubota, that the compositions of the invention promote healing, and the teachings of Tautvydas et al., that compositions comprising polyblock hydrophobic/hydrophilic copolymers may include radiopaque material and be implanted into lumens, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing implants. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Len3

December 1, 2003

J. Venkat
JYOTHSNA VENKAT
PRIMARY EXAMINER
GROUP 1600